June 21, 2019

DePuy Synthes
Quinn McCarthy
Regulatory Affairs Specialist II
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K190750
Trade/Device Name: see page 3, List of Cleared Devices in K190750
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulatory Class: Class II
Product Code: HRS, KTT, KTW, LXT, JDO, JDP
Dated: March 22, 2019
Received: March 25, 2019

Dear Quinn McCarthy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure:

List of Cleared Devices in K190750

List of Cleared Devices in K190750

1. DePuy Synthes 4.5mm VA LCP Curved Condylar Plate System Line Extension - MR Conditional
2. DePuy Synthes 3.5 mm Quadrilateral Surface Plates - MR Conditional
3. DePuy Synthes 2.7 mm / 3.5 mm LCP Distal Fibula Plates -MR Conditional
4. DePuy Synthes 3.5 mm LCP Posteromedial Proximal Tibia Plate 10H/183mm -MR Conditional
5. DePuy Synthes TornoFiX Medial Distal Femur Plates - MR Conditional
6. DePuy Synthes 3.5mm LCP Distal Tibia T Plates – MR Conditional
7. DePuy Synthes 2.4/2.7 mm Locking Foot Module - MR Conditional
8. DePuy Synthes LCP Distal Femur Plates - MR Conditional
9. DePuy Synthes LCP Ankle Arthrodesis Plates - MR Conditional
10. DePuy Synthes LCP Proximal Tibia Plates Line Extension - MR Conditional
11. DePuy Synthes 3.5 / 4.5mm LCP Medial Proximal Tibia Plates - MR Conditional
12. DePuy Synthes LCP Modular Foot Plates - MR Conditional
13. DePuy Synthes LCP Dynamic Helical Hip System - MR Conditional
14. DePuy Synthes LCP Proximal Femur Hook Plates - MR Conditional
15. DePuy Synthes 3.5 mm Low Profile Pelvic Reconstruction Plate - MR Conditional
16. DePuy Synthes LCP Proximal Femur Plate and Screws - MR Conditional
17. DePuy Synthes 3.5mm Titanium LCP Proximal Tibia Plate - MR Conditional
18. DePuy Synthes Titanium 4.5 mm LCP Proximal Tibia Plating System - MR Conditional
19. DePuy Synthes Locking Compression Plate System- MR Conditional
20. DePuy Synthes LCP Distal Tibia Plates - MR Conditional
21. DePuy Synthes LCP Proximal Tibia Plate - MR Conditional
22. DePuy Synthes Modular Foot System - 2.7 mm Module - MR Conditional
23. DePuy Synthes Medial Distal Tibia Plates - MR Conditional
24. DePuy Synthes Modular Foot System- MR Conditional
25. DePuy Synthes Locking Calcaneal Plates - MR Conditional
26. DePuy Synthes Proximal Tibia Plating System - MR Conditional
27. DePuy Synthes DHS/DCS System Modification - MR Conditional
28. DePuy Synthes Titanium Alloy High Tibial Osteotomy (HTO) System - MR Conditional
29. DePuy Synthes Dynamic Hip Screw - MR Conditional
30. DePuy Synthes 2.7 mm Condylar Plate- MR Conditional

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190750

Device Name
DePuy Synthes Modular Mini Fragment LCP System - MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Modular Mini Fragment LCP System is intended for fixation of fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments, particularly in osteopenic bone. Examples include, but are not limited to, the hand, wrist, foot, and ankle.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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K190750

Device Name

DePuy Synthes 4.5mm VA LCP Curved Condylar Plate System Line Extension - MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes 4.5mm VA LCP Curved Condylar Plate System is indicated for buttressing multifragmentary distal femur fractures including: supra-condylar; intra-articular and extra-articular condylar fractures, periprosthetic fractures, fractures in normal or osteopenic bone, nonunions and malunions.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Device Name

DePuy Synthes 3.5MM QUADRILATERAL SURFACE PLATES - MR Conditional

Indications for Use *(Describe)*

DePuy Synthes 3.5mm Quadrilateral Surface Plates are indicated for quadrilateral surface comminution associated with acetabular fractures when used in conjunction with Synthes pelvic reconstruction plates.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Device Name

DePuy Synthes 2.7 MM/3.5 MM LCP DISTAL FIBULA PLATES - MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes 2.7 mm / 3.5 mm LCP Distal Fibula Plates are indicated for fractures, osteotomies, and non-unions of the metaphyseal and diaphyseal region of the distal fibula, especially in osteopenic bone.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Device Name

DePuy Synthes 3.5MM LCP POSTEROMEDIAL PROXIMAL TIBIA PLATE 10H/183MM - MR Conditional

Indications for Use *(Describe)*

DePuy Synthes 3.5mm LCP Posteromedial Proximal Tibia Plates are indicated for internal fixation of posteromedial proximal tibia fractures including buttressing of fractures of the proximal, distal, and metaphyseal areas of the tibia.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Device Name
DePuy Synthes TOMOFIX MEDIAL DISTAL FEMUR PLATES - MR Conditional

Indications for Use *(Describe)*
DePuy Synthes TornoFiX Osteotomy System is intended for open and closed wedge osteotomies of the medial proximal tibia, lateral proximal tibia, medial and lateral distal femur, treatment of bone and joint deformities, fractures, and malalignment caused by injury or disease such as osteoarthritis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Device Name

DePuy Synthes 3.5MM LCP DISTAL TIBIA T PLATES - MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes LCP Distal Tibia T Plates are indicated for fractures, osteotomies, and non-unions of the distal tibia, especially in osteopenic bone.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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K190750

Device Name

DePuy Synthes 2.4/2.7 MM LOCKING FOOT MODULE - MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes 2.4/2.7 mm Locking Foot Module is intended for fixation of fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments, including the foot and ankle, particularly in osteopenic bone.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Device Name
DePuy Synthes LCP DISTAL FEMUR PLATES - MR Conditional

Indications for Use *(Describe)*
DePuy Synthes LCP Distal Femur Plates are intended for buttressing multifragmentary distal femur fractures including: supracondylar, intra-articular and extra-articular condylar, periprosthetic fractures and fractures in normal or osteopenic bone, nonunions and malunions, and osteotomies of the femur.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Device Name

DePuy Synthes LCP ANKLE ARTHRODESIS PLATES - MR Conditional

Indications for Use *(Describe)*

DePuy Synthes LCP Ankle Arthrodesis Plates are intended for arthrodesis of the ankle joint and distal tibia.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Device Name

DePuy Synthes LCP PROXIMAL TIBIA PLATES LINE EXTENSION - MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes LCP Proximal Tibia System is intended for treatment of nonunions, malunions, osteopenic bone, tibial osteotornies (4.5mm plate only), and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, periprosthetic, and fractures with associated shaft fractures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Device Name

DePuy Synthes 3.5/4.5MM LCP MEDIAL PROXIMAL TIBIA PLATES - MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes 3.5 / 4.5mm LCP Medial Proximal Tibia Plates are intended to buttress metaphyseal fractures of the medial tibia plateau, split-type fractures of the medial tibia plateau, medial split fractures with associated depressions and split or depression fractures of the medial tibia plateau. The plates may also be used for fixation of the proximal quarter (lateral and medial) of the tibia as well as segmental fractures of the proximal tibia. The 4.5mm version may also be used for fixation of nonunions and malunions of the medial proximal tibia and tibia shaft, as well as opening and closing wedge tibial osteotomnies.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Device Name
DePuy Synthes LCP MODULAR FOOT PLATES - MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes LCP Modular Foot Plates are intended for use in selective trauma, fractures, osteotomies, reconstructive procedures and replantations of small bones including the foot and ankle.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*

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Device Name
DePuy Synthes LCP DYNAMIC HELICAL HIP SYSTEM - MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes LCP Dynamic Helical Hip System is intended to treat stable and unstable intertrochanteric, subtrochanteric and basilar neck fractures in which a stable medial buttress can be reconstructed.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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K190750

Device Name
DePuy Synthes LCP PROXIMAL FEMUR HOOK PLATES - MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes LCP Proximal Femur Hook Plates are intended for fractures of the femur including: fractures of the trochanteric region, trochanteric simple, cervicotrochanteric, trochanterodiaphyseal, multifragmentary pertrochanteric, intertrochanteric, intertrochanteric reversed, or transverse or with additional fracture of medial cortex. Fractures of the proximal end of the femur combined with ispsilateral shaft fractures, metastatic fracture of the proximal femur and osteotomies of the proximal femur.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190750

Device Name

DePuy Synthes 3.5 MM LOW PROFILE PELVIC RECONSTRUCTION PLATE - MR Conditional

Indications for Use *(Describe)*

DePuy Synthes 3.5 Low Profile Pelvic Reconstruction Plate is intended for pelvic and acetabular reconstructive surgery and fracture fixation of the distal humerus, clavicle, and scapula.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*

K190750

Device Name

DePuy Synthes LCP PROXIMAL FEMUR PLATE AND SCREWS - MR Conditional

Indications for Use *(Describe)*

DePuy Synthes LCP Proximal Femur Plate is intended for fractures of the femur including: fractures of the trochanteric region, trochanteric simple, cervicotrochanteric, trochanterodiaphyseal, multifragmentary pertrochanteric, intertrochanteric, intertrochanteric reversed, or transverse or with additional fracture of medial cortex. Fractures of the proximal end of the femur combined with ispsilateral shaft fractures, metastatic fracture of the proximal femur and osteotomies of the proximal femur.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*

K190750

Device Name

DePuy Synthes 3.5MM TITANIUM LCP PROXIMAL TIBIA PLATES - MR Conditional

Indications for Use *(Describe)*

DePuy Synthes 3.5mm Titanium LCP Proximal Tibia Plate is intended for treatment of non-unions, malunions, and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression, and fractures with associated shaft fractures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*

K190750

Device Name

DePuy Synthes 4.5 MM TITANIUM LCP PROXIMAL TIBIA PLATING SYSTEM - MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes Titanium 4.5 mm LCP Proximal Tibia Plating System is intended for treatment of nonunions, malunions, and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression medial wedge, bicondylar, combination of lateral wedge and depression, and fractures with associated shaft fracture.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*

K190750

Device Name
DePuy Synthes LCP DISTAL TIBIA PLATES - MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Locking Compression Plate (LCP) System is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula, particularly in osteopenic bone. The DePuy Synthes LCP Distal Tibia Plates are intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal tibia and other small bones as a part of the DePuy Synthes Small Fragment LCP System.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*

K190750

Device Name
DePuy Synthes LCP PROXIMAL TIBIA PLATE - MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes LCP Proximal Tibia Plate is intended for treatment of non-unions, malunions, and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression, and fractures with associated shaft fractures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*

K190750

Device Name
DePuy Synthes MODULAR FOOT SYSTEM - 2.7 MM MODULE - MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Modular Foot System - 2.7 mm Module is intended for fractures, osteotomies, fusions and replantations of small bones including the foot, ankle, and hand.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*

K190750

Device Name
DePuy Synthes MEDIAL DISTAL TIBIA PLATES- MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Medial Distal Tibia Plates are indicated for the fixation of fractures of the distal tibia including, but not limited to, ankle fractures, periarticular, intraarticular and distal tibia fractures with a shaft extension, malleolar and distal fibular fractures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*

K190750

Device Name
DePuy Synthes Modular Foot System- MR Conditional

Indications for Use *(Describe)*
DePuy Synthes Modular Foot System is intended for fractures, osteotomies, and replantations of small bones including the foot, ankle, and hand.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*

K190750

Device Name

DePuy Synthes LOCKING CONDYLAR PLATE (LCP) SYSTEM- MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes Locking Condylar Plate (LCP) System is intended for buttressing multifragmentary distal femur fractures including: supracondylar, intra-articular and extra-articular condylar fractures, fractures in normal or osteopenic bone, and non-unions and malunions.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*

K190750

Device Name

DePuy Synthes LOCKING CALCANEAL PLATES - MR Conditional

Indications for Use *(Describe)*

DePuy Synthes Locking Calcaneal Plates are indicated for fractures and osteotomies of the calcaneus, including, but not limited to extra-articular, intra-articular, joint depression, tongue type and severely comminuted fractures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Device Name
DePuy Synthes PROXIMAL TIBIA PLATING SYSTEM - MR Conditional

Indications for Use *(Describe)*
The DePuy Synthes Proximal Tibia Plating System is intended for non-unions, malunions, and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression, and fractures with associated shaft fractures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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K190750

Device Name
DePuy Synthes DHS/DCS SYSTEM MODIFICATION - MR Conditional

Indications for Use *(Describe)*
DePuy Synthes DHS/DCS One-Step Lag Screws are designed for use with the Dynamic Hip Screw (DHS) Plates and Dynamic Condylar Screw (DCS) Plates. They are intended to treat stable and unstable intertrochanteric, subtrochanteric and basilar neck fractures in which a stable medial buttress can be reconstructed.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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K190750

Device Name

DePuy Synthes TITANIUM (TI) ALLOY HIGH TIBIAL OSTEOTOMY (HTO) SYSTEM - MR Conditional

Indications for Use *(Describe)*

DePuy Synthes Titanium Alloy High Tibial Osteotomy (HTO) System is an instrument and implant system intended to correct leg malalignments causing unicompartmental osteoarthritis, by correction of the tibial component. It utilizes a locking feature that secures the screw to the plate, enabling stable fixation to be achieved via unicortical or bicortical fixation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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K190750

Device Name

DePuy Synthes DYNAMIC HIP SCREW - MR Conditional

Indications for Use *(Describe)*

The DePuy Synthes DHS is indicated for the following fractures of the proximal femur:

- Intertrochanteric fractures
- Subtrochanteric fractures
- Basilar neck fractures

The DHS is indicated for stable fractures, and unstable fractures in which a stable medial buttress can be reconstructed.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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1. 510(k) Summary

Date Prepared: March 22, 2019

1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes 4.5mm VA LCP Curved Condylar Plate System Line Extension – MR Conditional

Classification Name(s): Condylar Plate Fixation Implant

Regulatory Class: Class II

Product Code(s): JDP, HWC

1.3. Predicate Device

K162124 - Synthes 4.5mm VA LCP Curved Condylar Plate System Line Extension

1.4. Device Description

The DePuy Synthes 4.5mm VA LCP Curved Condylar Plate System consists of anatomically-contoured, stainless steel and titanium plates and screws featuring variable angle locking and combi-holes designed to provide stable fixation of the distal femur and system specific instrumentation. The current 510(k) introduces OPTILINK™ Technology stainless steel screws, positioning pins for cerclage cable, and system specific instrumentation as a line extension to the currently cleared Synthes 4.5mm VA LCP Curved Condylar Plate System.

1.5. Indications for Use

The DePuy Synthes 4.5mm VA LCP Curved Condylar Plate System is indicated for buttressing multifragmentary distal femur fractures including: supra-condylar; intra-articular and extra-articular condylar fractures, periprosthetic fractures, fractures in normal or osteopenic bone, nonunions and malunions.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K162124. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes 4.5mm VA LCP Curved Condylar Plate System Line Extension in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 22, 2019

1.1. Submitter

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qmccarth@its.jnj.com

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Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes 3.5mm Quadrilateral Surface Plates – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II

Product Code(s): HRS

1.3. Predicate Device

K093928 - SYNTHES 3.5MM QUADRILATERAL SURFACE PLATES

1.4. Device Description

DePuy Synthes 3.5mm Quadrilateral Surface Plates consist of metallic plates pre-shaped to fit the quadrilateral surface of the pelvis. The plates are provided in shodt, standard, and long versions.

1.5. Indications for Use

DePuy Synthes 3.5mm Quadrilateral Surface Plates are indicated for quadrilateral surface comminution associated with acetabular fractures when used in conjunction with Synthes pelvic reconstruction plates.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K093928. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes 3.5mm Quadrilateral Surface Plates in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 22, 2019

1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes 2.7 mm/3.5 mm LCP Distal Fibula Plates – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II

Product Code(s): HRS, HWC

1.3. Predicate Device

K083213 - SYNTHES 2.7 MM/3.5 MM LCP DISTAL FIBULA PLATES

1.4. Device Description

DePuy Synthes 2.7 mm/3.5 mm LCP Distal Fibula Plates are contoured to match the anatomy of the distal fibula and diaphyseal region. The plates feature a low-profile design and Combi holes (Dynamic Compression Plate holes combined with locking screw holes), which accept 3.5 mm cortex, 3.5 mm self-tapping cortex, 3.5 mm shaft, 3.5 mm locking screws, and 4.0 mm cancellous screws. The plates locking holes accept 2.4 mm, 2.7 mm locking screws along with 2.4 mm and 2.7 mm self-tapping cortex screws. The plates are available in stainless steel and titanium, as well as a variety of lengths.

1.5. Indications for Use

The DePuy Synthes 2.7 mm/3.5 mm LCP Distal Fibula Plates are indicated for fractures, osteotomies, and non-unions of the metaphyseal and diaphyseal region of the distal fibula, especially in osteopenic bone.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K083213. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes 2.7 mm/3.5 mm LCP Distal Fibula Plates in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes 3.5mm LCP Posteromedial Proximal Tibia Plates – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II

Product Code(s): HRS

1.3. Predicate Device

K082624 - SYNTHES (USA) 3.5MM LCP POSTEROMEDIAL PROXIMAL TIBIA PLATES

1.4. Device Description

The DePuy Synthes 3.5mm LCP Posteromedial Proximal Tibia Plates are pre-contoured bone fixation plates intended for the treatment of fractures of the tibia. The plates are offered sterile and non-sterile and are available in stainless steel and titanium.

1.5. Indications for Use

DePuy Synthes 3.5mm LCP Posteromedial Proximal Tibia Plates are indicated for internal fixation of posteromedial proximal tibia fractures including buttressing of fractures of the proximal, distal, and metaphyseal areas of the tibia.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K082624. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes 3.5mm LCP Posteromedial Proximal Tibia Plates in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 22, 2019

1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes TomnoFiX Medial Distal Femur Plates – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II

Product Code(s): HRS

1.3. Predicate Device

K081353 - SYNTHES (USA) TOMOFIX MEDIAL DISTAL FEMUR PLATES

1.4. Device Description

The DePuy Synthes TomnoFiX Medial Distal Femur Plates are part of the Synthes TomnoFiX Osteotomny System which is a system consisting of titanium plates with locking and combination holes designed to provide stable fixation of osteotornies close to the knee. The TomoFiX Medial Distal Femur Plates consist of titanium plates anatomically contoured to fit the medial distal femur. The plates are available in right and left versions and feature locking holes in the head and combination locking/dynamic compression holes in the shaft.

1.5. Indications for Use

DePuy Synthes TornoFiX Osteotomy System is intended for open and closed wedge osteotomies of the medial proximal tibia, lateral proximal tibia, medial and lateral distal femur, treatment of bone and joint deformities, fractures, and malalignment caused by injury or disease such as osteoarthritis.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K081353. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes TomnoFiX Medial Distal Femur Plates in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 22, 2019

1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes 3.5 mm LCP Distal Tibia T Plates – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II

Product Code(s): HRS

1.3. Predicate Device

K080522 - SYNTHES 3.5MM LCP DISTAL TIBIA T PLATES

1.4. Device Description

DePuy Synthes 3.5 mm LCP Distal Tibia T Plates are contoured to match the anatomy of the distal tibia. The plates have both combination and locking screw holes which accept various Synthes screws. They are available in stainless steel and titanium, in a variety of lengths.

1.5. Indications for Use

The DePuy Synthes LCP Distal Tibia T Plates are indicated for fractures, osteotomies, and non-unions of the distal tibia, especially in osteopenic bone.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K080522. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes 3.5 mm LCP Distal Tibia T Plates in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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Date Prepared: March 22, 2019

1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes 2.4/2.7 mm Locking Foot Module – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II

Product Code(s): HRS

1.3. Predicate Device

K071264 - SYNTHES (USA) 2.4/2.7 MM LOCKING FOOT MODULE

1.4. Device Description

DePuy Synthes 2.4/2.7 mm Locking Foot Module consists of locking foot plates of various shapes and sizes to accommodate patient anatomy and orthopedic conditions in the foot and ankle. The plates are attached to bone via 2.4 and 2.7 mm cortex and locking screws.

1.5. Indications for Use

The DePuy Synthes 2.4/2.7 mm Locking Foot Module is intended for fixation of fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments, including the foot and ankle, particularly in osteopenic bone.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K071264. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes 2.4/2.7 mm Locking Foot Module in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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Date Prepared: March 22, 2019

1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes LCP Distal Femur Plates – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II

Product Code(s): HRS

1.3. Predicate Device

K062564 - SYNTHES LCP DISTAL FEMUR PLATES

1.4. Device Description

DePuy Synthes LCP Distal Femur Plates are part of the Synthes Locking Compression Plate (LCP) System. The plates have a low profile design, are available in left and right versions with Dynamic Compression Plate (DCP) holes combined with locking screw holes in the shaft of the plate and threaded screw holes in the head of the plate. The plates will be offered in stainless steel and titanium and will be available in sterile and non-sterile versions.

1.5. Indications for Use

DePuy Synthes LCP Distal Femur Plates are intended for buttressing multifragmentary distal femur fractures including: supracondylar, intra-articular and extra-articular condylar,

periprosthetic fractures and fractures in normal or osteopenic bone, nonunions and malunions, and osteotomies of the femur.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K062564. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes LCP Distal Femur Plates in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 22, 2019

1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes LCP Ankle Arthrodesis Plates – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II

Product Code(s): HRS

1.3. Predicate Device

K061940 - DePuy Synthes LCP Ankle Arthrodesis Plates

1.4. Device Description

DePuy Synthes LCP Ankle Arthrodesis Plates are minimally contoured metal plates that utilize locking screw technology to promote fusion or "arthrodesis" of the ankle. The plates will be offered in stainless steel and commercially pure titanium and will be available in sterile and non-sterile versions.

1.5. Indications for Use

DePuy Synthes LCP Ankle Arthrodesis Plates are intended for arthrodesis of the ankde joint and distal tibia.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K061940. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes LCP Ankle Arthrodesis Plates in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 22, 2019

1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes LCP Proximal Tibia System Line Extension – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II

Product Code(s): HRS

1.3. Predicate Device

K052390 - SYNTHES LCP PROXIMAL TIBIA PLATES LINE EXTENSION

1.4. Device Description

The DePuy Synthes LCP Proximal Tibia System are contoured to match the anatomy of the proximal tibia with a limited contact low profile design. These are plates designed for either the right or left tibia in a variety of shaft lengths. The plates have overall lengths ranging from 298 nun to 370 mm and shaft holes ranging from 16 to 20 holes.

1.5. Indications for Use

The DePuy Synthes LCP Proximal Tibia System is intended for treatment of nonunions, malunions, osteopenic bone, tibial osteotornies (4.5mm plate only), and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge,

bicondylar combination of lateral wedge and depression, periprosthetic, and fractures with associated shaft fractures.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K052390. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes LCP Proximal Tibia System in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 22, 2019

1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes (USA) 3.5 / 4.5 mm LCP® Medial Proximal Tibia Plates – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II

Product Code(s): HRS

1.3. Predicate Device

K050646 - SYNTHES (USA) 3.5/4.5MM LCP MEDIAL PROXIMAL TIBIA PLATES

1.4. Device Description

The DePuy Synthes (USA) 3.5 / 4.5 mm LCP® Medial Proximal Tibia Plates are contoured to match the anatomy of the medial proximal tibia with a limited contact low profile design. The plates are designed for either the right or left medial proximal tibia in a variety of shaft lengths. These plates will be available in both 3.5 mm and 4.5 mm versions. The plate head exhibits 2.0 mm holes for preliminary fixation with k-wires, or meniscal repair with sutures.

1.5. Indications for Use

The DePuy Synthes 3.5 / 4.5 mm LCP Medial Proximal Tibia Plates are intended to buttress metaphyseal fractures of the medial tibia plateau, split-type fractures of the medial tibia plateau, medial split fractures with associated depressions and split or depression fractures of the medial tibia plateau. The plates may also be used for fixation of the proximal quarter (lateral and medial) of the tibia as well as segmental fractures of the proximal tibia. The 4.5mm version may also be used for fixation of nonunions and malunions of the medial proximal tibia and tibia shaft, as well as opening and closing wedge tibial osteotomnies.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K050646. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes (USA) 3.5 / 4.5 mm LCP® Medial Proximal Tibia Plates in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

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1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes LCP Modular Foot Plates – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II

Product Code(s): HRS

1.3. Predicate Device

K050110 - SYNTHES (USA) LCP MODULAR FOOT PLATES

1.4. Device Description

DePuy Synthes LCP Modular Foot Plates consist of locking cuboid, navicular and talus plates used to treat small bone fractures. The plates are attached to bone via 2.4 and 2.7 mm cortex and locking screws.

1.5. Indications for Use

The DePuy Synthes LCP Modular Foot Plates are intended for use in selective trauma, fractures, osteotomies, reconstructive procedures and replantations of small bones including the foot and ankle.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K050110. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes LCP Modular Foot Plates in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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Date Prepared: March 22, 2019

1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes LCP Dynamic Helical Hip System – MR Conditional

Classification Name(s): Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component

Regulatory Class: Class II

Product Code(s): KTT

1.3. Predicate Device

K033556 - SYNTHES (USA) LCP DYNAMIC HELICAL HIP SYSTEM

1.4. Device Description

DePuy Synthes LCP Dynamic Helical Hip System is a plate and screw system that consists of a straight plate with an angled barrel that accepts a helical blade. T1he plates have a grooved undersurface, contain combination locking and dynamic compression holes and are available in various barrel angles and plate lengths. The sideplate combination holes accept 5.0 mim locking screws and 4.5 mim cortex screws.

1.5. Indications for Use

The DePuy Synthes LCP Dynamic Helical Hip System is intended to treat stable and unstable intertrochanteric, subtrochanteric and basilar neck fractures in which a stable medial buttress can be reconstructed.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K033556. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes LCP Dynamic Helical Hip System in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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Date Prepared: March 22, 2019

1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes LCP Proximal Femur Hook Plates – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II

Product Code(s): HRS

1.3. Predicate Device

K032032 - SYNTHES (USA) LCP PROXIMAL FEMUR HOOK PLATES

1.4. Device Description

The DePuy Synthes LCP Proximal Femur Hook Plates are contoured to match the anatomy of the proximal femur with a limited contact low profile design. The plate has dynamic compression holes combined with conical shaped threaded screw holes, which accept 4.5 mm cortex, 4.5 mm shaft screws, 4.0 mm or 5.0 mm locking screws, 5.0mm cannulated screws, and 7.3 mm cannulated locking & cannulated conical screws. The plates are available in a various lengths

1.5. Indications for Use

The DePuy Synthes LCP Proximal Femur Hook Plates are intended for fractures of the femur including: fractures of the trochanteric region, trochanteric simple, cervicotrochanteric, trochanterodiaphyseal, multifragmentary pertrochanteric, intertrochanteric, intertrochanteric reversed, or transverse or with additional fracture of medial cortex. Fractures of the proximal end of the femur combined with ispsilateral shaft fractures, metastatic fracture of the proximal femur and osteotomies of the proximal femur.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K032032. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes LCP Proximal Femur Hook Plates in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes 3.5 mm Low Profile Pelvic Reconstruction Plates – MR Conditional

Classification Name(s): Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component

Regulatory Class: Class II

Product Code(s): KTT, HRS

1.3. Predicate Device

K031573 - SYNTHES 3.5 MM LOW PROFILE PELVIC RECONSTRUCTION PLATE

1.4. Device Description

DePuy Synthes 3.5 mm Low Profile Pelvic Reconstruction Plates consist of curved plates and straight plates that are contourable in three planes. The plates have a smooth, rounded profile. Plate holes are slightly oval, allowing 30 degrees of angulation in all directions. The 3.5 mm Low Profile Reconstruction Plate accepts Synthes 3.5 mm Cortex Screws and Synthes 3.5 mm Pelvic Screws.

1.5. Indications for Use

DePuy Synthes 3.5 mm Low Profile Pelvic Reconstruction Plates is intended for pelvic and acetabular reconstructive surgery and fracture fixation of the distal humerus, clavicle, and scapula

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K031573. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes 3.5 mm Low Profile Pelvic Reconstruction Plates in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 22, 2019

1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes LCP Proximal Femur Plate – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II

Product Code(s): HRS, HWC

1.3. Predicate Device

K030858 - SYNTHES (USA) LCP PROXIMAL FEMUR PLATE AND SCREWS

1.4. Device Description

The DePuy Synthes LCP Proximal Femur Plate are contoured to match the anatomy of the proximal femur with a limited contact low profile design. The plate has dynamic compression holes combined with conical shaped threaded screw holes, which accept 4.5 mm cortex, 4.5 mm shaft screws, 4.0 mm or 5.0 mm locking screws, and 7.3 mm cannulated locking & cannulated conical screws. The plates and screws are available in a various lengths.

1.5. Indications for Use

DePuy Synthes LCP Proximal Femur Plate is intended for fractures of the femur including: fractures of the trochanteric region, trochanteric simple, cervicotrochanteric,

trochanterodiaphyseal, multifragmentary pertrochanteric, intertrochanteric, intertrochanteric reversed, or transverse or with additional fracture of medial cortex. Fractures of the proximal end of the femur combined with ispsilateral shaft fractures, metastatic fracture of the proximal femur and osteotomies of the proximal femur.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K030858. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes LCP Proximal Femur Plate in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

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1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes 3.5mm Titanium LCPTM Proximal Tibia Plates – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II

Product Code(s): HRS

1.3. Predicate Device

K030597 - SYNTHES 3.5MM TITANIUM LCP PROXIMAL TIBIA PLATES

1.4. Device Description

The DePuy Synthes 3.5mm Titanium LCPTM Proximal Tibia Plates are contoured to match the anatomy of the proximal tibia with a limited contact low profile design. The plates are designed for either the right or left tibia and are available in a variety of lengths. The plates are svailable in a variety of lengths.

The proximal portion of the plate head accepts 3.5mm titanium locking screws, the distal portion of the plate accepts 3.5 mm titanium locking screws, 3.5 mm titanium cortex screws, or 4.0 mm titanium sancellous bone screws.

1.5. Indications for Use

DePuy Synthes 3.5mm Titanium LCP Proximal Tibia Plate is intended for treatment of non-unions, malunions, and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression, and fractures with associated shaft fractures.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K030597. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes 3.5mm Titanium LCPTM Proximal Tibia Plates in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 22, 2019

1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes Titanium 4.5mm LCP Proximal Tibia Plating System – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II

Product Code(s): HRS

1.3. Predicate Device

K023802 - SYNTHES 4.5 MM TITANIUM LCP PROXIMAL TIBIA PLATING SYSTEM

1.4. Device Description

The DePuy Synthes Titanium 4.5mm LCP Proximal Tibia Plating System consists of 4.5 mm Titanium LCP Proximal Tibia Plates, 5.0 mm Titanium Cannulated Locking and Conical screws, and 4.0 mm and 5.0 mm Titanium Solid Locking screws.

The Tibia Plates are contoured to match the anatomy of the proximal tibia with a limited contact low profile design. These are plates designed for either the right or left tibia in a variety of shaft lengths. The plate head has threaded screw holes and 2.0 mm holes for preliminary fixation with kwires, or meniscal repair with sutures.

The plate shaft has combination screw holes (dynamic compression and locking screw holes), that accept 4.5 mm cortex, 6.5 mm cancellous, 5.0 mm cannulated locking, 5.0 mm conical, and 4.0 mm & 5.0 mm locking screws. A titanium screw nut is also utilized with this system

1.5. Indications for Use

The DePuy Synthes Titanium 4.5mm LCP Proximal Tibia Plating System is intended for treatment of nonunions, malunions, and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression medial wedge, bicondylar, combination of lateral wedge and depression, and fractures with associated shaft fracture.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K023802. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Titanium 4.5mm LCP Proximal Tibia Plating System in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 22, 2019

1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes Locking Compression Plate (LCP) System – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II

Product Code(s): HRS

1.3. Predicate Device

K013248 - SYNTHES LCP DISTAL TIBIA PLATES

1.4. Device Description

The DePuy Synthes Locking Compression Plate (LCP) System are machined metallic plates that offer screw to plate locking designed for various fracture modes of the distal end of the tibia and other small bones.

1.5. Indications for Use

The DePuy Synthes Locking Compression Plate (LCP) System is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula, particularly in osteopenic bone. The DePuy Synthes LCP Distal Tibia Plates are intended for fixation of complex intra- and extra-articular fractures and osteotomies

of the distal tibia and other small bones as a part of the DePuy Synthes Small Fragment LCP System.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K013248. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Locking Compression Plate (LCP) System in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 22, 2019

1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes LCP Proximal Tibia Plates – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II

Product Code(s): HRS

1.3. Predicate Device

K011978 - SYNTHES LCP PROXIMAL TIBIA PLATE

1.4. Device Description

The DePuy Synthes LCP Proximal Tibia Plates are contoured to match the anatomy of the proximal tibia with a limited contact low profile design. There are plates designed for either the right or left tibia in a variety of shaft lengths. These plates will be available in both 3.5 mm and 4.5 mm versions. The plates are available in a variety of lengths.

The locking screw holes accept both cannulated locking and conical screws. Two proximal round holes accept cortex screws, cancellous screws, or cannulated screws. The distal portion of the plate has combination dynamic compression locking screw holes that allow the option of using locking screws, cortex screws, or cannulated screws.

1.5. Indications for Use

The DePuy Synthes LCP Proximal Tibia Plate is intended for treatment of non-unions, malunions, and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression, and fractures with associated shaft fractures.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K011978. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes LCP Proximal Tibia Plates in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 22, 2019

1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes Modular Foot System - 2.7 mm Module – MR Conditional

Classification Name(s): Appliance, Fixation, Nail/Blade/Plate Combination, Single Component

Regulatory Class: Class II

Product Code(s): KTW

1.3. Predicate Device

K010321 - MODULAR FOOT SYSTEM - 2.7 MM MODULE

1.4. Device Description

The DePuy Synthes Modular Foot System - 2.7 mm Module is a series of plates having various lengths, thickness, and configurations including L-, T-, HindiMidfoot, Calcaneal Reconstruction, Quarter Tubular, LC-DCP, and MTP Fusion Plates. These plates are attached to bone via 2.7 mm selftapping cortex screws.

1.5. Indications for Use

The DePuy Synthes Modular Foot System - 2.7 mm Module is intended for fractures, osteotomies, fusions and replantations of small bones including the foot, ankle, and hand.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K010321. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Modular Foot System - 2.7 mm Module in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 22, 2019

1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes Medial Distal Tibia Plates are – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II

Product Code(s): HRS

1.3. Predicate Device

K001945 - SYNTHES (USA) MEDIAL DISTAL TIBIA PLATES

1.4. Device Description

DePuy Synthes Medial Distal Tibia Plates are available in two sizes: 3.5 mm and 4.5 mm. They are pre-contoured to fit the distal tibia anatomy. The plates feature a limited contact - dynamic compression plate design and are available (LC-DCP) in right and left versions. The end of the plate includes a hole for a suture, if necessary. The plates accept 3.5 mm, 4.0 mm, 4.5 min cortex screws, and 4.0 min cancellous screws.

1.5. Indications for Use

DePuy Synthes Medial Distal Tibia Plates are indicated for the fixation of fractures of the distal tibia including, but not limited to, ankle fractures, periarticular, intraarticular and distal tibia fractures with a shaft extension, malleolar and distal fibular fractures.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K001945. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Medial Distal Tibia Plates are in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 22, 2019

1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes Modular Foot System – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II

Product Code(s): HRS

1.3. Predicate Device

K001941 - Synthes Modular Foot System

1.4. Device Description

DePuy Synthes Modular Foot System is a series of plates and screws with plates of varying lengths and thicknesses and configurations including T-, LC-DCP, Condylar, and Cuboid Plates. These plates are attached to bone via 1.8 mm buttress pins and 2.0 mm and 2.4 mm self-tapping cortex screws.

1.5. Indications for Use

DePuy Synthes Modular Foot System is intended for fractures, osteotomies, and replantations of small bones including the foot, ankle, and hand.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K001941. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Modular Foot System in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 22, 2019

1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes (USA) 3.5/4.5 mm LCP Medial Proximal Tibia Plates – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II

Product Code(s): HRS, HTY, HWC, JDW

1.3. Predicate Device

K000066 - SYNTHES (USA) LOCKING CONDYLAR PLATE (LCP) SYSTEM

1.4. Device Description

DePuy Synthes (USA) 3.5/4.5 mm LCP Medial Proximal Tibia Plates is a plate and screw system. The primary feature of the plate and screw system is that the locking screws engage with the head and shaft of the plate to form a locked, fixed angle construct. The system features limited-contact profile, dynamic compression unit (DCU) and locking screw holes.

1.5. Indications for Use

The DePuy Synthes Locking Condylar Plate (LCP) System is intended for buttressing multifragmentary distal femur fractures including: supracondylar, intra-articular and extra-

articular condylar fractures, fractures in normal or osteopenic bone, and non-unions and malunions.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K000066. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes (USA) 3.5/4.5 mm LCP Medial Proximal Tibia Plates in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 22, 2019

1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes Locking Calcaneal Plates – MR Conditional

Classification Name(s): Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component, Metal Composite

Regulatory Class: Class II

Product Code(s): LXT

1.3. Predicate Device

K991407 - SYNTHES LOCKING CALCANEAL PLATES

1.4. Device Description

DePuy Synthes LCPs are designed to address complex fractures of the calcaneus and are applied to the lateral side. The plate has 15 threaded screw holes, which accept 2.7 mm and 3.5 mm cortex screws, as well as 3.0 mm locking screws. The plates are 2.0 mm thick, 69 mm and 76 mm in length, and are available for right and left placements.

1.5. Indications for Use

DePuy Synthes Locking Calcaneal Plates are indicated for fractures and osteotomies of the calcaneus, including, but not limited to extra-articular, intra-articular, joint depression, tongue type and severely comminuted fractures.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K991407. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Locking Calcaneal Plates in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes Proximal Tibia Plating System – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II

Product Code(s): HRS

1.3. Predicate Device

K983787 - SYNTHES PROXIMAL TIBIA PLATING SYSTEM

1.4. Device Description

The DePuy Synthes Proximal Tibia Plating System consists of 3.5 mm and 4.5 mm Plates and a 3.5/4.5 mm Washer. The plates are anatomically contoured; feature a low profile, limited contact design, and are available in right and left versions. The heads of the plates include holes for K-wires or sutures, if necessary. The 3.5 mm Plates are used with 3.5 mm cortex, 4.0 mm cancellous, and 4.5 mm cannulated screws. The 4.5 mm Plates are used with 4.5 mm cortex, 6.5 mm cancellous, 7.0 mm and 7.3 mm cannulated screws. When used with the 3.5/4.5 washer, the 4.5 mm Plates can also be used with all of the screws that fit the 3.5 plates; the washer prevents the screw head from pulling through the plate holes. This device system is manufactured from stainless steel.

1.5. Indications for Use

The DePuy Synthes Proximal Tibia Plating System is intended for non-unions, malunions, and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression, and fractures with associated shaft fractures.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K983787. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Proximal Tibia Plating System in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes DHSIDCS One-Step Lag Screws SYSTEM MODIFICATION – MR Conditional

Classification Name(s): Device, Fixation, Proximal Femoral, Implant

Regulatory Class: Class II

Product Code(s): JDO, KTT

1.3. Predicate Device

K964259 - SYNTHES (USA) DDHS/DCS SYSTEM MODIFICATION

1.4. Device Description

The DePuy Synthes DHSIDCS One-Step Lag Screws have a 12.7 mm or a 14.0 mm thread diameter and are available in lengths ranging from 50 mm to 145 mm. The DHSIDCS One Step Lag Screws feature an internal broach drive mechanism. The DHSIDCS One Step Lag Screws are manufactured from stainless steel.

1.5. Indications for Use

DePuy Synthes DHS/DCS One-Step Lag Screws are designed for use with the Dynamic Hip Screw (DHS) Plates and Dynamic Condylar Screw (DCS) Plates. They are intended to treat stable and

unstable intertrochanteric, subtrochanteric and basilar neck fractures in which a stable medial buttress can be reconstructed.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K964259. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes DHSIDCS One-Step Lag Screws in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes Titanium Alloy HTO System – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II

Product Code(s): HRS

1.3. Predicate Device

K963325 - SYNTHES TITANIUM (TI) ALLOY HIGH TIBIAL OSTEOTOMY (HTO) SYSTEM

1.4. Device Description

DePuy Synthes Titanium Alloy HTO System is an instrument and implant system intended to correct leg malalignments causing unicompartmental osteoarthritis, by correction of the tibial component. It utilizes a locking feature that secures the screw to the plate, enabling stable fixation to be achieved via unicortical or bicortical fixation.

1.5. Indications for Use

DePuy Synthes Titanium Alloy High Tibial Osteotomy (HTO) System is an instrument and implant system intended to correct leg malalignments causing unicompartmental osteoarthritis, by correction of the tibial component. It utilizes a locking feature that secures

the screw to the plate, enabling stable fixation to be achieved via unicortical or bicortical fixation.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K963325. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Titanium Alloy HTO System in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

1. 510(k) Summary

Date Prepared: March 22, 2019

1.1. Submitter

Primary Contact:
Quinn McCarthy
Regulatory Affairs Specialist II
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-6730
qmccarth@its.jnj.com

Alternate Contact:
Elizabeth Jacobs
Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes Dynamic Hip Screw – MR Conditional

Classification Name(s): Plate, Fixation, Bone

Regulatory Class: Class II

Product Code(s): KTT

1.3. Predicate Device

K791619 - DYNAMIC HIP SCREW

1.4. Device Description

1.5. Indications for Use

The DePuy Synthes DHS is indicated for the following fractures of the proximal femur:
- Intertrochanteric fractures
- Subtrochanteric fractures
- Basilar neck fractures

The DHS is indicated for stable fractures, and unstable fractures in which a stable medial buttress can be reconstructed.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the K791619. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes Dynamic Hip Screw in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.

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DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
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qmccarth@its.jnj.com

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Regulatory Affairs Project Leader
DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380
Phone: (610) 719-5768
Ejacob10@its.jnj.com

1.2. Device

Name of Device: DePuy Synthes 2.7 mm Condylar Plate – MR Conditional

Classification Name(s): Single/multiple component bone fixation appliances and accessories

Regulatory Class: Class II

Product Code(s): HRS

1.3. Predicate Device

K063049 – DEPUY SYNTHES MODULAR MINI FRAGMENT LCP SYSTEM

1.4. Device Description

The plate has six holes in the shaft and one hole beside the blade. The blades are set at a 90° either to the left or right of a coaxial plate hole. All plates can be cut to the desired length with plate cutting forceps.

1.5. Indications for Use

The DePuy Synthes Modular Mini Fragment LCP System is intended for fixation of fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments, particularly in osteopenic bone. Examples include, but are not limited to, the hand, wrist, foot, and ankle.

1.6. Substantial Equivalence

The purpose of this submission is to add MR Conditional information to the device labeling for the Preamendment. The intended use and technological characteristics of the devices remains unchanged.

Non-clinical testing is provided to support the conditional safety of the DePuy Synthes 2.7 mm Condylar in the MR environment including assessment of magnetically induced displacement force (ASTM F2052-14) and torque (ASTM F2213-06), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety or efficacy.